PHILIPS

MAR 1 5 2002

Philips Medical Systems

K020055

510(k) SUMMARY

The following information is being submitted in accordance with the requirements of 21 CFR 807.92.

Company Name:	Philips Medical Systems North America Company
Address:	22100 Bothell Everett Highway P.O. Box 3003 Bothell, WA 98041-3003
Registration No.:	1217116
Contact Person:	Lynn Harmer
Telephone No.:	(425) 487-7312
Date Prepared:	January 7, 2002
Device (Trade) Name:	PHILIPS Integris Allura 9 system with FD Option
Classification Name:	Angiographic x-ray system, Class II, 90 IZI Solid x-ray Imager, Class II, 90 MBQ

Predicate Devices:

The Philips Integris Allura 9 System with FD Option is substantially equivalent to the Philips Integris H5000 system manufactured by Philips Medical Systems. The Integris H5000 received a 510(k) substantially equivalent determination in K984545 on February 25, 1999.

The FD option is also substantially equivalent to GE Medical Systems' solid state digital detector cleared by FDA on February 14, 2000, under 510(k) K993037.

Device Description:

The Philips Integris Allura 9 system with FD Option is an angiographic x-ray system with a solid state x-ray imaging device for cardiovascular diagnostic and interventional procedures. The monoplane system can be configured as either a floor or ceiling suspended G-arm frontal stand. The x-ray detector is comprised of amorphous silicon with a cesium iodide scintillator. The system supports generating and recording x-ray diagnostic images using fluoroscopic and fluorographic techniques. X-ray images are

22100 Bothell Everett Highway
Bothell, Washington 98021-8431
(425) 487 7000

detected with a flat dynamic x-ray detector (FD) and are recorded on digital storage medium. The system offers the functionality to review and analyze the images. Digital images with corresponding patient and examination data may be archived on film (video or laser hardcopy) or on digital storage media.

Indications for Use:

The Philips Integris Allura 9 system with FD Option is intended for use in cardiac x-ray imaging applications, including diagnostic, interventional procedures (such as PTCA, stent placing, atherectomies) pacemaker implantations, and electrophysiology.

General Safety and Effectiveness:

The devices and their labeling will comply with the applicable requirements of 21 CFR, Subchapter J - Radiological Health, parts 1020.30, .31, and .32.

The device will comply with applicable requirements of the Underwriters Laboratories Standard for Safety, X-ray Equipment (UL 187 and UL 2601) and be classified by Underwriters Laboratories. The Integris Allura 9 system with FD Option will also comply with the ACR/NEMA DICOM digital imaging communication standard.

Conclusion:

The Phillips Integris Allura 9 system with FD Option does not introduce any new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems considers the Integris Allura 9 system with FD Option to be substantially equivalent with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Lynn Harmer
Manager, Regulatory Submissions
Philips Medical Systems
22100 Bothell Everett Hwy.
BOTHELL WA 98041-3003

AUG 20 2013

Re: K020055
Trade/Device Name: Philips Integris Allura 9 System with FD Option
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA and IZI
Dated: January 7, 2002
Received: January 8, 2002

Dear Ms. Harmer:

This letter corrects our substantially equivalent letter of March 15, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K020055

Device Name: Philips Integris Allura 9 system with FD Option

Indications for Use:

The Philips Integris Allura 9 system with FD Option is intended for use in cardiac imaging applications including diagnostic, interventional procedures (such as PTCA, stent placing, atherctomies,) pacemaker implantations, and electrophysiology (EP.)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguren

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020055

Prescription Use √ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)